

UNOFFICIAL TRANSLATION

We are hereby referring to the document published on the APHIS-USDA Internet site entitled: "Biological Analysis: Risk Assessment & Management Options for Imports of Swine and Swine Products from the European Union".

This document, analyzed in its entirety, is probably at least as far as Italy is concerned, a step forward with regard to previous CSF health surveys conducted by American Authorities; it contains, however, some inaccuracies and erroneous evaluations that can become a risk for our exports in the U.S., especially when concerning swine products.

We therefore consider it necessary to aware the American Veterinarian Authorities aware of our opinions as well as our disagreements concerning the above-mentioned document, keeping in mind that they can only be considered by the APHIS-USDA if they are received before the publication of the final regulations concerning CSF for imports from the European Community.

In particular, we consider it necessary to point out the following:

1. On page 2 of the document in the "Geographic Scope of the Recommendations" paragraph, among the regions that run the highest CSF risk, Lombardy, Emilia-Romagna and Sardinia have been included. The parameters used by APHIS for this classification involved finding at least one CSF nidus in these regions within the last six months and the endemic presence of CSF among the wild boar population with the subsequent infection of domestic swine.

In reference to this, we need to point out that the Emilia-Romagna Region has reached CSF immunity status after the Fontevivo (Parma) nidus was eliminated in September, 1998. Moreover, this nidus was not linked to other ones and within the protection or surveillance areas, no serum-positive elements have been found which indicates a fast and efficient control of the infection.

In addition, there have been no endemic CSF cases found in wild boars in the region.

As far as the Lombardy region is concerned, throughout the course of 1998, no CSF nidus was found and those found in 1997 were almost all involving wild boars in the Varese province.

Therefore, in accordance with the same criteria used by APHIS-USDA, Lombardy should be excluded from the list of regions considered CSF infected as, in the last six months, no case of this disease has been

recorded. It could, however, be suggested that the U.S. Authorities regard the single Varese province as a "region". This hypothesis is supported by the regulations of the 64/432/CEE Guideline and its subsequent amendments that, for Italy, identifies within provinces, the administrative units which have effective control of and are responsible for the animals' health and movement. Moreover, it should be mentioned that the Varese province, from a veterinarian monitoring point of view, is a single unit, as this territory is under the jurisdiction of the Veterinary Service of the Varese Local Health Agency with a personnel of 44 public veterinarian officials.

2. On page 5 of the document, in the "Reliance of International Standards of the Office International des Epizooties" paragraph, with regard to an evaluation by the APHIS-USDA that refers to a publication by Dutch researchers emphasizing the necessity of imposing a 60 day quarantine period for live swine imported from the member countries of the European Union, a statement was made that Italy considers unacceptable. It says that the Dutch researchers estimated, for Italy and Spain, a 60.5 day average period, ranging from the beginning of the disease to the effective implementation of control measures.

In the month of August, 1998, after consulting with the Reference Center for Swine Infective Diseases at the IZS of Perugia and conducting a survey of epidemiological data on CSF nidi, the Department of Food/Nutrition and Veterinarian Public Health calculated that in 95% of the cases in Italy the above-mentioned period lasts 15 days and in the remaining 4-5% of the cases, lasts up to one month.

That period, therefore, is not a reflection of the real average time registered in Italy. On the contrary, we have no evidence that it has ever been registered in any nidus involving diseases from the O.I.E. A list.

The research was conducted in answer to an APHIS-USDA questionnaire – dated August 5, 1998 and sent by diplomatic mail to our Department – on the evaluation of CSF risk in Europe. The above-mentioned questionnaire expressly asks for an estimate for Italy of the "number of days from the infection's beginning up until the activation of control measures (percentage and mean). For instance, how long the virus was present before the health authorities were informed and proceeded with control measures".

We do not understand why this official data was not considered by the American Veterinarian Authorities.

3. On page 5 of the document, in the "Summary of qualitative evidence", clause 1 makes a statement that we consider unacceptable. It says that on European Community territory, there is no control over the movement of animals and animal products, except when the movement takes place in breeding farms where the disease has been recorded, or within protected or monitored areas. In general, therefore, the American Veterinarian Authorities should be informed of the fact that within the European Community, the movement of swine takes place on the base of health and official conditions established by the 64/432/CEE Guideline and its subsequent amendments which since 1964, among other things, have required (proof of) immunity from different diseases contracted in the original farms, and specific documentation to travel along with the animals. Moreover, upon arrival, some control measures are implemented at random based on the regulations established by the 90/425/CEE Guideline. In addition, all movement within the European Community territory is monitored by the computer network called "ANIMO System".
4. On page 24 of the document, the "Results for Fresh, Chilled, and Frozen Pork" paragraph says that the evaluation of the risk in regard to CSF introduction into the U.S. through pork products has taken place, keeping the epidemiological situation in the EU territory in mind, as if the situation were the same as in Holland during the 1997 epidemic outbreak. This is due to the fact that the APHIS-USDA supposedly did not receive data and information relating to CSF nidi that existed in the EU member countries during 1997. This does not seem likely considering that the Ministry has always provided all the information required by the American Authorities on CSF nidi existing in Italy. Moreover, epidemiological information has also been provided by the O.I.E. who had been quickly informed about the different nidi of diseases on the A list by the Department of Food/Nutrition and Veterinary Public Health.

CONCLUSION

A final and comprehensive evaluation of the APHIS-USDA document by this Ministry has no other choice but to have some reservations. In fact, even the mathematical calculations of the risk evaluation, although formally correct, from a scientific and methodological point of view, is affected by the fact that the basic theories and the data sources are incorrect.

Whereas this document, in its published form, is a partial obstacle for EU live swine, swine sperm, and especially as far as Italy is concerned, pork products exports into the U.S., we insist on the necessity of our country obtaining from the U.S. acknowledgement of CSf immunity for the Lombardy region, except for the "region" of the Varese province, and the Emilia-Romagna region.

We kindly request that you let the APHIS-USDA know that we will quickly proceed to directly send them all of the information requested in Appendix A2.